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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,771	10/16/2003	Martin Stelzle	WWELL78.006C1	9526

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	**PAPER NUMBER**
1753	

NOTIFICATION DATE	DELIVERY MODE
09/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/688,771	STELZLE ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *restriction election of 6/28/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-20,31-36,47-50,64-71 and 80-84* is/are pending in the application.

4a) Of the above claim(s) *64-71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-20,31,32,36,47-50 and 80-84* is/are rejected.

7)☒ Claim(s) *33-35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/16/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 18, 19, 31, 32, 36, 47, and 49 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Yadav et al. US 6,946,197 B2. See the abstract, Figure 1, and col. 06:14-17. Also see page 25 of 99, page 45 of 99, and page 46 of 99 in provisional application 60/242,905 from which US 6,946,197 B2 claims priority (the pages themselves indicate "20" (SBIR Phase I Final Report: Low Temperature, High Altitude Humidity sensor), "7", and "8" (SBIR Phase I Final Report: High Temperature Micromachined sensor for Industrial Gas Streams), respectively. However, the

provisional application is a collection of separately numbered documents that together have 99 pages and are labeled pages 1-99 in the Examiner's electronic file).

For claim 31 also note that barring a showing of some structural implication to the term "biosensor", which would distinguish it from the sensor of Yadav, the Examiner will construe this preamble qualification to just suggest an intended use without any additional structural requirements.

For claim 32 also note substrate 22 in Figure 1 (also shown, but not lagged on page 46 of 99 in 60/242,905).

3. Claims 18, 19, 31, 36, 47, 49, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Case et al. US 5,328,847 ("Case"). See the abstract, Figure 1, and col. 10:61 – col. 11:07, which implies a nanopore opening range that overlaps, if not includes the range of approximately 20 nm to approximately 1000 nm because Case discloses that the number of channels per mm^2 membrane area ma be in the range of from about 50 to about 10^9 for gramicidin D.

For claim 50 also note that a potentiostat is implied by col. 10:13-24, which discloses supplying the cell with a constant direct voltage in the poised state.

4. Claims 18, 19, 31, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Northrup et al. US 6,004,450 ("Northup"). See Figure 8 and col. 07:38-50.

Note that although the preamble claims a pair of measuring electrodes and the electrodes in the embodiment of Figure 8 in Northrup are for electrophoresis, barring a contrary showing, the pair of electrodes in Figure 8 could be used as measuring electrodes. In other words, that the pair of electrodes in claim 18 is for measuring is only an intended use that does not structurally differentiate the claimed invention from the embodiment of Figure 8 of Northrup.

Also note that even if electrode 74 in Figure 8 can be shown have nanopores as does electrode 73 and not be a continuously flat sheet so that an upper surface is exposed by the nanochannels (nanopores) 75, nanopores 75 will expose the inner wall of the nanopores of electrode 74 to fluid introduced through the nanopores 72.

For claim 31 also note that barring a showing of some structural implication to the term "biosensor", which would distinguish it from the sensor of Yadav, the Examiner will construe this preamble qualification to just suggest an intended use without any additional structural requirements.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 20 and 80-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yadav et al. US 6,946,197 B2. Yadav discloses a pair of measuring electrodes as set forth in claims 18 and 31. See the rejection of claims 18 and 31 under 24 U.S.C. 102 (e) above. Yadav does not, though, specifically mention letting the nanopores have an opening width of approximately 100 nm, or approximately 50nm, or approximately 200 nm. However, Yadav does disclose that the diameter of the nanopores "... is tunable in the range from 1 to 500 nanometers ..." See col. 06:14-18 (and in 60/242,905 the Figure 14 caption on page 18 of 99 and the last paragraph on page 45 of 99). Thus, barring evidence to the contrary, such as unexpected results, the selection of an opening width for the nanopores of particularly approximately 100 nm, or approximately 50nm, or approximately 200 nm is either arbitrary, or just a matter of optimization. As noted by Yadav pore size is related to sensing surface area and therefor sensitivity. See page 45 of 99, second full paragraph and the page 47 of 99, second full paragraph ("Depositing of sensitive ...").

9. Claims 20 and 80-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Case et al. US 5,328,847 ("Case"). Case discloses a pair of measuring electrodes as set forth in claims 18 and 31. See the rejections of claims 18 and 31 under 35 U.S.C. 102 (b) above. Case does not, though, specifically mention letting the nanopores have an opening width of approximately 100 nm, or approximately 50nm, or approximately 200 nm. However, implicitly Case does disclose that the diameter of the

nanopores may be less than 1000 nm since Case discloses that up to 10^9 channels (pores) may be provided per mm^2 of membrane area (col. 10:61-64). With this pore density the pore width must be less than 1,000 nm other wise the pores would have no pore walls (1 mm^2./ 109 = 1,000 nm^2). Thus, barring evidence to the contrary, such as unexpected results, the selection of an opening width for the nanopores of particualty approximately 100 nm, or approximately 50nm, or approximately 200 nm. is just a matter of optimization. As noted by Case the ion channel density (and thus pore size) is quadratically proportional to nominal concentration of the antibiotic. Large pore density (and thuds smaller pore size) "... is preferred for embodiments in which simplicity is more important in the measurement electronics." See col. 10:61 – col. 11:07. Also the insulating layer (membrane) chosen will depend on the sample as different insulating layers (membranes) will have different types of ion channels.

10. Claims 20 and 80-84 is rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al: US 6,004,450. Northrup discloses a pair of measuring electrodes as set forth in claims 18 and 31. See the rejections of claims 18 and 31 under 35 U.S.C. 102 (b) above. Northrup does not, though, specifically mention letting the nanopores have an opening width of approximately 100 nm, or approximately 50nm, or approximately 200 nm. However, Northrup does disclose that the diameter of the nanopores may be from about 1 μm down to about 10 nm. See col. 07:38-50. Thus,

barring evidence to the contrary, such as unexpected results, the selection of an opening width for the nanopores of particularly approximately 100 nm, or approximately 50nm, or approximately 200 nm is either arbitrary, or just a matter of optimizing or scaling of the pore volume to the sample size.

11. Claims 32 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Case et al. US 5,328,847 ("Case") in view of Gitler et al. US 5,204,239 ("Gitler"). Case discloses a pair of measuring electrodes as set forth in claim 18 and an electrochemical cell as set forth in claim 47. See the rejections of claim 18 and claim 47 under 35 U.S.C. 102 (b) above. Case does not, though, specifically mention having the at least one pair of measuring electrodes arranged on a substrate or having cell comprising a receiving space for an electrolyte, and wherein the electrolyte includes molecules to be recorded using the biosensor.

Gitler discloses a biosensor comprising a pair of electrodes (13,16) separated by a membrane bilayer comprising ion channels (14). Gitler further discloses arranging the pair of electrodes on a substrate (11). See the abstract; Figure 1A; col. 04:54-68. It would have been obvious to one with ordinary skill in the art at the time of the invention to arrange the pair of electrodes on a substrate as taught by Gitler in the invention of Case because this will protect the electrodes from electrical shorting and protect the

biosensor from mechanical damage or accidental contamination while it is moved and handled. Moreover, a substrate as taught by Gitler will, in addition to its protective functions, also provide a receiving space for an electrolyte, and wherein the electrolyte includes molecules to be recorded using the biosensor. See Figure 1A of Gitler. This will make the electrochemical cell of Case more convenient to use as it will not have be submerged into a beaker or other container when a measurement is to be made.

Allowable Subject Matter

12. Claims 33-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 33 – the combination of limitations requires "at least one additional electrode arranged on the substrate, wherein the additional electrode serves as a reference electrode or counterelectrode."

In Yadav each electrode in the electrode pair directly covers an opposing surface of the insulation layer. See Figure 1 (and Page 25 of 99 and page 46 of 99 in 60/242,905). A third electrode could not be arranged on the substrate without significant modification of the biosensor.

In Case as modified by Gitler each electrode in the electrode pair directly covers an opposing surface of the insulation layer. See Figure 1 of Case and Figure 1A of Gitler. A third electrode could not be arranged on the substrate without significant modification of the biosensor.

Giaver et al. US 5,187,096 teaches away from the invention of the pending independent claims because pores (28) through the insulating layer (26) implicitly "... have an area which is less than or equal to about 10^{-2} cm^2 , or advantageously 10^{-3} to 10^{-4} cm^2 ," (Figures 1 and 2 and col. 08:48-53) with 10^{-4} cm^2 equaling 10^{10} nm^2 , while the independent claims require the nanopores to have an opening width selected from the range of approximately 20 nm to approximately 1000 nm .

Fritsch et al. US 7,144,486 B1 teaches away from the invention of the pending independent claims because pores through the insulating layer may have a diameter as little as 10 micrometers or greater than 100 micrometers (col. 16:56 – col. 17:12), while the independent claims require the nanopores to have an opening width selected from the range of approximately 20 nm to approximately 1000 nm .

b) Claims 34 and 35 depend from allowable claim 33.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
September 14, 2007